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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH & LOMB, INC.; BAUSCH & LOMB IRELAND LIMITED; and EYE THERAPIES, LLC, Plaintiffs, v. SLAYBACK PHARMA LLC and SLAYBACK PHARMA INDIA LLP, Defendants.	Civil Action No. 21-16766 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Bausch & Lomb, Inc., Bausch & Lomb Ireland Limited, and Eye Therapies, LLC (collectively, "Plaintiffs") by way of Complaint against Defendants Slayback Pharma LLC and Slayback Pharma India LLP (collectively, "Defendants") allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent Nos. 8,293,742 ("the '742 patent") and 9,259,425 ("the '425 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Slayback Pharma LLC's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j)

of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic Brimonidine Tartrate Ophthalmic Solution, 0.025% ("Slayback's generic brimonidine ophthalmic solution") prior to the expiration of the '742 patent and the '425 patent.

THE PARTIES

2. Plaintiff Bausch & Lomb, Inc. ("Bausch") is a corporation organized and existing under the laws of New York with a place of business at 1400 N. Goodman St. Rochester, NY 14609. Bausch is the registered holder of approved New Drug Application ("NDA") No. 208144, which covers Lumify® ophthalmic solution/drops (brimonidine tartrate, 0.025%).

3. Plaintiff Bausch & Lomb Ireland Limited ("Bausch Ireland") is a company organized and existing under the laws of Ireland, having its registered office at 3013 Lake Drive, Citywest Business Park, Dublin, Ireland. Bausch Ireland exclusively licenses the '742 patent and the '425 patent.

4. Plaintiff Eye Therapies, LLC ("Eye Therapies") is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 26933 Camino De Estrella, 2nd Fl., Dana Point, California 92624. Eye Therapies is the owner of the '742 patent and the '425 patent.

5. Upon information and belief, Slayback Pharma, LLC ("Slayback") is a Delaware limited liability company having a principal place of business at 301 Carnegie Center, Suite 303, Princeton, NJ 08540, within this judicial district.

6. Upon information and belief, Slayback Pharma India LLP ("Slayback India") is a limited liability partnership organized under the laws of India, having a principal place of business

at 310, 3rd Floor, Manjeera Trinity Corporate, JNTU - Hitech City Road, KPHB Phase 3, Kukutpally Hyderabad, Telangana 500072, India.

7. Upon information and belief, Slayback is the parent corporation of Slayback India, and the acts of Slayback complained of herein were done with the cooperation, participation and assistance of Slayback India.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

9. Upon information and belief, this court has jurisdiction over Slayback. Upon information and belief, Slayback is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Slayback directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Slayback's generic brimonidine ophthalmic solution. Upon information and belief, Slayback purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Slayback has its principal place of business at 301 Carnegie Center, Suite 303, Princeton, New Jersey 08540. Upon information and belief, Slayback has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Upon information and belief, Slayback has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at, upon information and belief, the State of New

Jersey and elsewhere. Slayback's ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Slayback intends to direct sales of its drugs into New Jersey, among other places, once it has the requested FDA approval to market them. Upon information and belief, Slayback will engage in marketing of its generic brimonidine ophthalmic solution in New Jersey upon approval of its ANDA.

11. Upon information and belief, this court has jurisdiction over Slayback India. Upon information and belief, Slayback India is in the business of, *inter alia*, developing, manufacturing, marketing, importing and selling pharmaceutical products, including generic drug products. Upon information and belief, Slayback India directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Slayback's generic brimonidine ophthalmic solution. Upon information and belief, Slayback India purposefully has conducted and continues to conduct business in this judicial district in concert with Slayback.

12. Upon information and belief, Slayback and Slayback India operate as interrelated corporate entities. Upon information and belief, Slayback is the parent corporation of Slayback India. Upon information and belief, Slayback and Slayback India each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

13. Defendants know or should know that Lumify® is manufactured for Bausch, at least because that information is included in the label for Lumify® and is publicly available.

14. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

15. Venue is proper against Slayback Pharma, LLC, which maintains a regular and established place of business in this judicial district.

16. Venue is proper against Slayback India, a foreign corporation, in any judicial district that has personal jurisdiction, including this judicial district.

THE PATENTS IN SUIT

17. The PTO issued the '742 patent on October 23, 2012. The '742 patent claims, *inter alia*, methods of reducing eye redness consisting essentially of administering brimonidine into ocular tissue. Plaintiffs hold all substantial rights in the '742 patent and have the right to sue for infringement thereof. A copy of the '742 patent is attached hereto as Exhibit 1.

18. The U.S. Patent and Trademark Office ("PTO") issued the '425 patent on February 16, 2016. The '425 patent claims, *inter alia*, methods of reducing redness of an eye and/or increasing whiteness of an eye comprising administering compositions comprising brimonidine. Plaintiffs hold all substantial rights in the '425 patent and have the right to sue for infringement thereof. A copy of the '425 patent is attached hereto as Exhibit 2.

19. Bausch is the holder of NDA No. 208144 for Lumify®, which the FDA approved on December 22, 2017. In conjunction with NDA No. 208144, the '742 and '425 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

20. Brimonidine tartrate ophthalmic solution, 0.025%, is sold in the United States under the trademark Lumify®.

SLAYBACK'S INFRINGING ANDA SUBMISSION

21. Upon information and belief, Slayback filed or caused to be filed with the FDA ANDA No. 216361, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

22. Upon information and belief, Slayback's ANDA No. 216361 seeks FDA approval to engage in commercial manufacture, use, and sale in the United States of Slayback's generic brimonidine ophthalmic solution, intended to be a generic version of Lumify®.

23. On or about August 16, 2021, Plaintiffs received a letter from Slayback dated August 13, 2021, purporting to be a Notice of Paragraph IV Certification regarding ANDA No. 216361 ("Slayback's Notice Letter") under Section 505(j)(2)(B)(iv) of the Act and 21 § C.F.R. 314.95. Slayback's Notice Letter was addressed to Bausch and Eye Therapies.

24. Slayback's Notice Letter alleges that Slayback has submitted to the FDA ANDA No. 216361 seeking approval to engage in the commercial manufacture, use and/or sale of Slayback's generic brimonidine ophthalmic solution, intended to be generic versions of Lumify®.

25. Slayback's Notice Letter states that Slayback's ANDA No. 216361 contains the "required bioavailability or bioequivalence data or information with respect to brimonidine tartrate ophthalmic solution, 0.025%," for Slayback's generic brimonidine ophthalmic solution.

26. Upon information and belief, ANDA No. 216361 seeks approval of Slayback's generic brimonidine ophthalmic solution that is the same, or substantially the same, as Lumify®.

27. Upon information and belief, Slayback's actions related to ANDA No. 216361 complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of Slayback India.

COUNT I FOR PATENT INFRINGEMENT

Infringement of the '742 Patent Under § 271(e)(2)

28. Paragraphs 1-27 are incorporated herein as set forth above.

29. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '742 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216361 seeking

approval for the commercial marketing of Slayback's generic brimonidine ophthalmic solution before the expiration date of the '742 patent.

30. Upon information and belief, Slayback's generic brimonidine ophthalmic solution will, if approved and marketed, infringe at least one claim of the '742 patent.

31. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Slayback's generic brimonidine ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '742 patent.

32. If Defendants' marketing and sale of Slayback's generic brimonidine ophthalmic solution prior to the expiration of the '742 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the '742 Patent

33. Paragraphs 1-32 are incorporated herein as set forth above.

34. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

35. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

36. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Slayback's generic brimonidine ophthalmic solution before the expiration date of the '742 patent, including Slayback's filing of ANDA No. 216361.

37. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Slayback's generic brimonidine ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '742 patent.

38. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Slayback's generic brimonidine ophthalmic solution will constitute infringement of at least one claim of the '742 patent.

COUNT III FOR PATENT INFRINGEMENT

Infringement of the '425 Patent Under § 271(e)(2)

39. Paragraphs 1-38 are incorporated herein as set forth above.

40. Under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the '425 patent by submitting, or causing to be submitted to the FDA, ANDA No. 216361 seeking approval for the commercial marketing of Slayback's generic brimonidine ophthalmic solution before the expiration date of the '425 patent.

41. Upon information and belief, Slayback's generic brimonidine ophthalmic solution will, if approved and marketed, infringe at least one claim of the '425 patent.

42. Upon information and belief, Defendants will, through the manufacture, use, import, offer for sale, and/or sale of Slayback's generic brimonidine ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '425 patent.

43. If Defendants' marketing and sale of Slayback's generic brimonidine ophthalmic solution prior to the expiration of the '425 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV FOR PATENT INFRINGEMENT

Declaratory Judgment of Infringement of the ’425 Patent

44. Paragraphs 1-43 are incorporated herein as set forth above.

45. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

46. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

47. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Slayback’s generic brimonidine ophthalmic solution before the expiration date of the ’425 patent, including Slayback’s filing of ANDA No. 216361.

48. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Slayback’s generic brimonidine ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’425 patent.

49. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer of use, sale, and/or importation of Slayback’s generic brimonidine ophthalmic solution will constitute infringement of at least one claim of the ’425 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor and against Defendants on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’742 patent by submitting or causing to be submitted ANDA No. 216361 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Slayback’s generic brimonidine ophthalmic solution before the expiration of the ’742 patent

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Defendants have infringed at least one claim of the ’425 patent by submitting or causing to be submitted ANDA No. 216361 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Slayback’s generic brimonidine ophthalmic solution before the expiration of the ’425 patent;

3. Order that the effective date of any approval by the FDA of Slayback’s generic brimonidine ophthalmic solution be a date that is not earlier than the expiration of the ’425 patent and the ’742 patent, or such later date as the Court may determine;

4. Enjoin Defendants from the commercial manufacture, use, import, offer for sale, and/or sale of Slayback’s generic brimonidine ophthalmic solution until expiration of the ’742 patent and the ’425 patent, or such later date as the Court may determine;

5. Enjoin Defendants and all persons acting in concert with Slayback from seeking, obtaining, or maintaining approval of Slayback’s ANDA No. 216361 until expiration of the ’742 patent and the ’425 patent;

6. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney’s fees; and

7. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: September 10, 2021
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.
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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: September 10, 2021
Newark, New Jersey

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